UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

LEON D. BOROCHOFF, On Behalf of Himself and All Others Similarly Situated, Plaintiff, vs. GLAXOSMITHKLINE PLC, et al., Defendants.	Civil Action No. 1:07-cv-05574-LLS CLASS ACTION MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' MOTION FOR RECONSIDERATION OF THE COURT'S OPINION AND ORDER, DATED MAY 9, 2008

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Pursuant to Local Civil Rule 6.3 and Fed. R. Civ. P. 59(e) and 60(b), Lead Plaintiff Avon Pension Fund, Administered by Bath & North East Somerset Council and Plaintiffs Plumbers & Steamfitters Local 773 Pension Fund and Plumbers' Union Local No. 12 Pension Fund (collectively, "Plaintiffs") respectfully submit this memorandum of law in support of their motion for reconsideration of the Court's Opinion and Order, dated May 9, 2008 (the "Decision"; attached hereto as Exhibit A), which granted the motion to dismiss the Amended Class Action Complaint (the "AC") filed by Defendants GlaxoSmithKline plc ("Glaxo" or the "Company"), Jean-Pierre Garnier, Ph.D. ("Garnier"), David Stout ("Stout"), Julian Heslop and Simon Bicknell (collectively, "Defendants") and resulted in a Judgment against Plaintiffs being entered on May 13, 2008.

I. PRELIMINARY STATEMENT

On May 13, 2008, this Court dismissed the AC, with prejudice. The Court held, *inter alia*, that Glaxo did not have a duty to disclose the Meta-Analyses[1] and that Plaintiffs failed to adequately plead scienter. Decision, p. 15 and 21.[2] Plaintiffs have filed a motion for reconsideration and respectfully ask this Court to reconsider its Decision and permit Plaintiffs to amend the AC.

In the Decision, the Court faulted Plaintiffs for failing to allege that "heart attack risk was either statistically significant or sufficiently serious or frequent to affect Avandia's future earnings." Decision, p. 15. The Court also held that the AC did not sufficiently allege scienter because, *inter alia*, "this case does not present facts indicating a clear duty to disclose. . . ." Decision, p. 21. Plaintiffs respectfully submit that the additional allegations in the [Proposed] Second Amended Complaint (the "PSAC"; attached hereto as Exhibit B) correct the defects cited in the Decision by

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1 Capitalized terms are as defined in the AC and PSAC (defined below).

2 "Decision, p. __" refers to pages of the Court's Decision, dated May 9, 2008.

alleging that: (i) the Meta-Analyses showed that the use of Avandia presented an increased risk of heart attack and that this increased risk was statistically significant; (ii) Glaxo has failed to submit Avandia-related study data to the FDA on numerous occasions; and (iii) Avandia sales have plummeted, among other additions detailed herein. *See* ¶¶5; 10; 11; 43-47.[3]

Justice requires that the Court permit Plaintiffs the opportunity to correct the deficiencies cited by the Court in the Decision and which Plaintiffs can clearly remedy, as evidenced by the PSAC. Given the new factual allegations regarding Glaxo's intimidation of Dr. John Buse ("Buse"), the statistically significant results of the Meta-Analyses, Glaxo's failure to submit Avandia-related study data to the FDA on numerous occasions and the dramatically declining sales of Avandia – information which was largely unavailable at the time Plaintiffs filed the AC – it is respectfully submitted that the Court should reconsider the Decision and vacate that portion of the Decision which dismisses the AC with prejudice and permit Plaintiffs the opportunity to replead the AC to include the new allegations, as set forth in the PSAC.

II. NEW ALLEGATIONS IN THE PSAC

The PSAC contains numerous allegations concerning new evidence and further details the allegations of the AC. *See* ¶¶4; 7; 10; 11; 35-47.

First, the PSAC fully details Glaxo's intimidation of Buse. ¶¶4; 7; 35-42; 78. As detailed in the PSAC, at the time that Avandia was approved by the FDA, Buse, a well-known independent scientist, raised concerns that the use of Avandia could lead to adverse cardiovascular events. Glaxo responded by complaining to Buse's superiors at the University of North Carolina and by threatening litigation. Eventually, Glaxo was successful in intimidating Buse and stopping him from publicly

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[3] "¶__" refers to paragraphs of the PSAC.

raising concerns about Avandia and adverse cardiovascular events. Instead of taking the necessary steps to investigate the concerns raised by Buse, Glaxo acted to protect its Avandia franchise by concealing, for as long as possible, the connection between Avandia and adverse cardiovascular events. Glaxo's actions towards Buse evidence that the Company viewed any public statement linking use of Avandia to adverse cardiovascular events as highly detrimental for sales of the drug. *See* ¶¶4; 7; 35-42; 78.[4]

Furthermore, the PSAC alleges that, in May 2007, the United States Senate Committee on Finance (the "Finance Committee") held hearings to investigate accusations that Glaxo had intimidated or attempted to silence medical professionals who had raised concerns about the potential for cardiovascular problems with Avandia. In November 2007, the Finance Committee issued a report entitled "The Intimidation of Dr. John Buse and the Diabetes Drug Avandia." In the report, the Finance Committee described the findings of its investigation in detail. The Finance Committee found that, in 1999, Buse had expressed concerns regarding the cardiovascular risks – including heart attacks – associated with Avandia. Glaxo was not only knowledgeable about the link between Avandia and heart attacks, but, according to the Finance Committee's report, Defendants Garnier and Stout, as well as then research chief for the Company, Tachi Yamada, were participants in a concerted effort to intimidate Buse and silence his efforts to publicize Avandia's potential negative cardiovascular effects. The Finance Committee's report stated that Glaxo stifled Buse by complaining to his superiors at the University of North Carolina, calling him a "renegade" and ultimately threatening him with the prospect of facing a lawsuit.

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[4] Although the Court addressed certain aspects of the Buse-related allegations in the Decision, the PSAC fully develops those allegations and places them in context. It is respectfully submitted that when this is done, the Buse-related allegations support Plaintiffs' fraud allegations.

Second, the PSAC alleges that the Meta-Analyses concluded that the use of Avandia presented an increased risk of heart attack and that this increased risk was statistically significant. ¶¶5; 6; 43-46. The PSAC further alleges that the FDA's own analysis of the 42 clinical trials that Glaxo used in the Meta-Analyses concluded that the use of Avandia increased the risk of cardiovascular events, which was statistically significant. Finally, the PSAC alleges that the meta-analysis completed by Dr. Steven Nissen ("Nissen"), which was based on virtually the same data as the Meta-Analyses, concluded that the use of Avandia presented a risk of heart attack that was statistically significant. ¶¶6; 69.[5]

Third, the PSAC alleges that the FDA has cited Glaxo for failing to properly report Avandia-related study information to the FDA and noted that Glaxo's reporting practices were not conducive to the FDA's monitoring of safety trends. On March 25, 2008, the FDA issued a warning letter to Glaxo (the "FDA Warning Letter"; attached hereto as Exhibit C) which stated, among other things, that Glaxo had "failed to report data relating to clinical experience, along with other data and information, for Avandia, as required" by applicable regulations. In addition, the FDA Warning Letter indicated that Glaxo had failed to report nine Avandia-related studies to the FDA and that those studies were not disclosed to the FDA until Glaxo made an amendment to its 2007 NDA Annual Report in September 2007. ¶¶10; 80.

Finally, the PSAC details the dramatically declining sales of Avandia due to Nissen's meta-analysis and the FDA's safety alert. On October 24, 2007, Glaxo announced that it would be implementing layoffs and cost cuts after a 38% drop in sales of Avandia significantly hurt the

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[5] Defendants have previously argued that the results of the Meta-Analyses were inconclusive. Decision, p. 19. This contention is directly refuted by the FDA's conclusions finding statistical significance and Nissen's meta-analysis, which also found statistical significance. At a minimum, Defendants have raised a factual issue which can not be decided on a motion to dismiss.

Company's third quarter earnings. On February 7, 2008, Glaxo reported a 12% drop in fourth quarter profit and warned that earnings for 2008 would drop as well, hurt by declining sales of Avandia. Sales of Avandia for the fourth quarter dropped 29% in the U.S. amid concerns that the drug could pose cardiovascular risks. On April 23, 2008, Glaxo announced its financial results for the first quarter of 2008 and reported that Avandia sales had declined 56%, with sales in the U.S. down 66%, sales in Europe down 14% and sales in international markets down 44%. In short, Avandia sales have plummeted after it was revealed that a meta-analysis evidenced a connection between Avandia and an increased risk of heart attack. ¶¶11; 71; 89.

II. ARGUMENT

A. The Applicable Legal Standards on a Motion for Reconsideration

A court may reconsider a prior ruling on the following grounds: "(1) an intervening change in controlling law; (2) the availability of newly discovered evidence; and (3) the need to correct clear error or to prevent manifest injustice." *Excess Ins. Co. v. Odyssey Am. Reinsurance Corp.*, No. 05 Civ. 10884 (NRB), 2008 U.S. Dist. LEXIS 30585 (S.D.N.Y. Mar. 26, 2008); *see also B.H. v. Southington Bd. of Educ.*, No. 3:02 cv 252 (SRU), 2004 U.S. Dist. LEXIS 237 (D. Conn. Jan. 7, 2004) ("[T]he function of a motion for reconsideration is to present the court with an opportunity to correct manifest errors of law or to consider newly discovered evidence.") (internal citations omitted); Fed. R. Civ. P. 59 & 60. The doctrine for granting a motion for reconsideration "is a discretionary rule of practice and generally does not limit a court's power to reconsider an issue." *In re PCH Assocs.*, 949 F.2d 585, 592 (2d Cir. 1991); *see also Bonnie & Co. Fashions v. Bankers Trust Co.*, 955 F. Supp. 203, 209 (S.D.N.Y. 1997) (stating that it is within a court's discretion "to reconsider an issue if the court deems such reconsideration appropriate").

A plaintiff is entitled to introduce new evidence if the plaintiff shows that: "(1) the evidence was newly discovered since the trial; (2) the moving party was diligent in discovering the new

evidence; (3) the newly discovered evidence could not be merely cumulative or impeaching; (4) the newly discovered evidence was material; and (5) that a new trial, with the newly discovered evidence, will probably produce a different result." *Geressy v. Digital Equip. Corp.*, 980 F. Supp. 640, 646 (E.D.N.Y. 1997) (granting 59(e) motion where noteworthy publicity became available only after the trial); *Gavenda v. Orleans County*, No. 95-CV-0251E(Sc), 2000 U.S. Dist. LEXIS 13915 (W.D.N.Y. Sept. 21, 2000) (citing the *Geressy* standard).

Where alleged new evidence is concerned, the legal standards under Rule 59(a)(2) and Rule 60(b)(2)[6] are identical. *See Burzynski v. Travers*, 111 F.R.D. 15, 16 n.1 & 18 (E.D.N.Y. 1986). "In order to obtain relief on the basis of newly discovered evidence, the moving party must demonstrate not only that the evidence existed at the time of the prior action and that it justifiably was not available to the movant . . . but also that the evidence would be admissible and of such import as probably to have changed the result in the prior action." *In re Donald Sheldon & Co.*, 222 B.R. 690, 693 (S.D.N.Y. 1998); *see also LiButti v. United States*, 178 F.3d 114, 119 (2d Cir. 1999) (stating that a motion to reconsider will be granted providing that alleged new evidence must change the outcome).

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[6] Rule 60(b) states:

> On motion and upon such terms as are just, the court may relieve a party or a party's legal representative from a final judgment, order, or proceeding for the following reasons: (1) mistake, inadvertence, surprise, or excusable neglect; (2) newly discovered evidence which by due diligence could not have been discovered in time to move for a new trial under Rule 59(b); (3) fraud (whether heretofore denominated intrinsic or extrinsic), misrepresentation, or other misconduct of an adverse party; (4) the judgment is void; (5) the judgment has been satisfied, released, or discharged, or a prior judgment upon which it is based has been reversed or otherwise vacated, or it is no longer equitable that the judgment should have prospective application; or (6) any other reason justifying relief from the operation of the judgment.

Here, the Decision resulted in a Judgment being entered on May 13, 2008. This motion has therefore been timely made. *See* Local Civil Rule 6.3. It is respectfully submitted that based on the new evidence described herein as well as the other proposed amendments to the AC, the Court, in the interest of justice, should permit Plaintiffs to amend the AC and file the PSAC. *See* Fed. R. Civ. P. 15 ("The court should freely give leave when justice so requires."); *Wells v. Harris*, 185 F.R.D. 128, 131 (D. Conn. 1999) (embracing the language contained in Rule 15(a), specifically that leave to amend pleadings is to be "freely given when justice so requires," and adding that "[i]t is 'rare' that leave to amend should be denied"); *cf. Sileo v. Principal Life Ins. Co.*, 29 Fed. Appx. 765, 766 (2d Cir. 2002) (acknowledging that "leave to replead should be granted freely where justice so requires," yet ruled against the right to replead on the basis that there was no "indication in the record that [plaintiff] requested leave to amend the complaint").

B. Plaintiffs Should Be Permitted to Amend the AC

Plaintiffs should be permitted to amend the allegations of the AC. Leave to replead is routinely granted, particularly where the party seeking leave has expressed an intention to allege additional facts. *See Chill v. GE*, 101 F.3d 263, 271 (2d Cir. 1996) ("In general, leave to amend should be freely granted, especially where dismissal of the complaint was based on Rule 9(b), and there must be good reason to deny the motion.") (internal citations omitted); *Radha Bhavatarini Devi Narumanchi v. Fed. Emergency Mgmt. Agency*, No. 99-6139, 1999 U.S. App. LEXIS 30444 (2d Cir. 1999) ("In general, leave to amend 'should be freely granted, especially where dismissal . . . was based on Rule 9(b).'") (quoting *Chill*, 101 F.3d at 271); *Initial Pub. Offering Sec. Litig.*, 241 F. Supp. 2d 281, 397 (S.D.N.Y. 2003) ("leave to replead should be granted when a complaint is dismissed."). Furthermore, in this complex securities-fraud lawsuit, and in "this technical and demanding corner of the law, the drafting of a cognizable complaint can be a matter of trial and error." *Eminence Capital, L.L.C. v. Aspeon, Inc.*, 316 F.3d 1048, 1052 (9th Cir. 2003); *Belizan v.*

Hershon, 434 F.3d 579, 584 (D.C. Cir. 2006) (because PSLRA's text does not state that dismissal for failure to meet pleading standards should be with prejudice, "we are governed simply by Rule 15(a), which . . . allows 'maximum opportunity for each claim to be decided on its merits'") (internal citations omitted).

Here, Plaintiffs have provided the Court with the PSAC, which sets forth the additional factual allegations that Plaintiffs respectfully submit address the deficiencies the Court identified in the Decision. In the interests of justice, it is respectfully submitted that the Court should give Plaintiffs leave to amend the AC.

1. The PSAC Alleges that the Meta-Analyses Provided Statistically Significant Evidence that Use of Avandia Increased the Risk of Heart Attacks

In the Decision, the Court, citing the Second Circuit's decision in *In re Carter-Wallace, Inc. Sec. Litig.*, 150 F.3d 153 (2d. Cir. 1998), held that Defendants did not have a duty to disclose the Meta-Analyses because "the Amended Complaint nowhere alleges that GSK's Meta-Analyses results provided statistically significant evidence that Avandia caused cardiovascular risks." Decision, p. 12-13. The PSAC now alleges that the Meta-Analyses showed that the use of Avandia presented an increased risk of heart attack and this increased risk was statistically significant. Moreover, the PSAC further alleges that the FDA's own analysis of the 42 clinical trials that Glaxo used in the Meta-Analyses concluded that the use of Avandia presented a "statistically significant" risk of cardiovascular events. Finally, the PSAC alleges that the meta-analysis completed by Nissen, which was based on virtually the same data as the Meta-Analyses, concluded that the use of Avandia presented a risk of heart attack which was statistically significant. ¶¶6; 69. Considered in their totality, these allegations sufficiently allege that the Meta-Analyses provided statistically significant evidence that the use of Avandia increased the risk of heart attacks.

Furthermore, the PSAC's new allegations about Glaxo's intimidation of Buse sufficiently allege that Defendants were aware that any public mention of a connection between the use of Avandia and the increased risk of heart attack would negatively impact future sales of Avandia. *See* ¶¶4; 7; 35-42; 78; 84. Indeed, as detailed in the PSAC, based on the public release of Nissen's meta-analysis and the FDA safety alert, sales of Avandia have plummeted by as much as 50%. ¶¶11; 71; 89.

In sum, it is respectfully submitted that the PSAC corrects the deficiencies cited in the Decision and meets the disclosure standards set forth in the Decision.

2. The PSAC Adds Allegations that Contribute to a Strong Inference of Scienter

The Decision also held that the AC failed to adequately allege scienter, noting that "because, as discussed earlier, this case does not present facts indicating a clear duty to disclose, plaintiff's scienter allegations do not provide strong evidence of conscious misbehavior or recklessness." Decision, p. 21. As set forth above, the PSAC now sufficiently alleges that Defendants had a duty to disclose the Meta-Analyses.

In addition, the PSAC adds allegations about the intimidation of Buse and the FDA Warning Letter, which both support a strong inference of scienter. The intimidation of Buse contributes to a strong inference of scienter, as it evidences that Defendants were concerned about the public disclosure of any connection between Avandia and an increased risk of heart attack and took steps to ensure that Buse's concerns were silenced.[7] The Finance Committee has issued a report criticizing

[7] The PSAC also pleads additional detail relating to scienter, specifically pleading Defendants' motivation behind concealing the truth about the dangers associated with Avandia. Avandia's sales have plummeted since the truth about the risk of heart attacks linked with the drug has become public and Defendants were motivated to protect and preserve those sales. As such, Defendants

Glaxo's intimidation of Buse and concluding that the Company actively sought to silence Buse. ¶¶7; 78.

Furthermore, the FDA Warning Letter rebuts Defendants' contention that Glaxo shared all information with the FDA. In fact, the FDA notes that results from nine Avandia studies were not provided to the FDA when the studies were completed and that other important studies were not provided to the FDA through the proper channels, which would have permitted the FDA staff to monitor safety trends. The concealment of test data from the FDA, as set forth in the FDA Warning Letter, further supports Plaintiffs' scienter allegations.

III. CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that the Court reconsider its Decision and permit Plaintiffs the opportunity to amend the AC.

DATED: May 28, 2008

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failed to disclose the information in their possession about the risk of heart attacks as a side-effect of Avandia.

CERTIFICATE OF SERVICE

I, Samuel H. Rudman, hereby certify that on May 28, 2008, I caused a true and correct copy of the attached:

> Notice of Motion for Reconsideration of the Court's Opinion and Order, Dated May 9, 2008; and
>
> Memorandum of Law in Support of Plaintiffs' Motion for Reconsideration of the Court's Opinion and Order, Dated May 9, 2008,

to be served: (i) electronically on all counsel registered for electronic service for this case; and (ii) by first-class mail to any additional counsel.

/s/ Samuel H. Rudman
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GLAXOSMITHKLINE 07

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